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75690 77597 19768/2008 EXAMINER GENOMICS INSTITUTE OF THE NOVARTIS RESEARCH FOUNDATION 10675 JOHN JAY HOPKINS DRIVE, SUITE E225 SAN DIEGO, CA 92121-1127  EXAMINER SHLAQ REI TSANG ART UNIT PAPER:	APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
GENOMICS INSTITUTE OF THE EXAMINER NOVARTIS RESEARCH FOUNDATION SHAO, RELEASAN 10675 JOHN JAY HOPKINS DRIVE, SUITE E225 SAN DIEGO, CA 92121-1127 LE26  ART UNIT PAPER:	10/590,618	08/24/2006	Shifeng Pan	P1152US10	2237	
NOVARTIS RESEARCH FOUNDATION 10675 JOHN JAY HOPKINS DRIVE, SUITE E225 SAN DIEGO, CA 92121-1127  1626  SHEAR REL TRANS SHEAR REL TRANS 1640 ART UNIT PAPER 1 1626			EXAM	EXAMINER		
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NOTIFICATION DATE DELIVER			1626			
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					DELIVERY MODE ELECTRONIC	

## Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IPLegal@gnf.org jclarke@gnf.org

# Office Action Summary

Application No.	Applicant(s)	
10/590,618	PAN ET AL.	
Examiner	Art Unit	
REI-TSANG SHIAO	1626	

	REI-TSANG SHIAO	1626					
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING D. Extensions of time may be available under the provisions of 3 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication.  If NO period for reply is geofficial above, the mainfund statutory period very considered to the provision of the provision of Any reply received by the Office later than three months after the mailing aemed patent term adjustment. See 37 CFR 1.70(4b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim- rill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE!	N. nely filed the mailing date of this o D (35 U.S.C. § 133).					
Status							
Responsive to communication(s) filed on 24 Ar      This action is FINAL.      Since this application is in condition for allowar closed in accordance with the practice under E	action is non-final. nce except for formal matters, pro		e merits is				
Disposition of Claims							
4) \( \text{ Claim(s)} \frac{1.14}{1.16} \text{ is/are pending in the application.} \) 4a) Of the above claim(s) is/are withdraw 5) \( \text{ Claim(s)} is/are allowed.} \) 6) \( \text{ Claim(s)} is/are rejected.} \) 7) \( \text{ Claim(s)} is/are objected to.} \) 8) \( \text{ Claim(s)} \frac{1.14}{1.14} \text{ are subject to restriction and/or } \)	vn from consideration.						
Application Papers							
9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) acc Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Ex	epted or b) objected to by the E drawing(s) be held in abeyance. See ion is required if the drawing(s) is obj	a 37 CFR 1.85(a). jected to. See 37 C					
Priority under 35 U.S.C. § 119							
12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) ☐ All b) ☐ Some * c) ☐ None of:  1. ☐ Certified copies of the priority documents have been received in Application No  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.							
Attachment(s)							
1) Notice of References Cited (PTO-892)	Interview Summary     Paper No(s)/Mail Da						

 Notice of Draftsperson's Patent Drawing Review (PT
 Information Disclosure Statement(s) (PTO/SE/08) Paper No(s)/Mail Date \_\_\_\_\_.

5) Notice of Informal Patent Application 6) Other:

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#### DETAILED ACTION

1. Claims 1-14 are pending in the application.

#### Election/Restriction

2. Restriction is required under 35 U.S.C. 121 and 372.

### Lack of Unity Requirement

- This application contains the following inventions or groups of inventions, which are not so linked as to form a single inventive concept under PCT Rule 13.1.
- Claims 1-14, in part, drawn to compounds/compositions of formula (I), wherein
  the variable m is 2, the variable n is 1 thereof; the variable E is CR8 or N thereof;
  when the variable Y represent heteroaryl selected from the moiety defined in

claim 8 thereof, i.e.,

variable X represent heteroaryl selected from the moiety defined in claim 4 thereof, i.e.,

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thereof; R1-R5 independently do <u>not</u> represent heteroaryl or heterocycloalkyl thereof, the variables R1-R5 independently are not substituted with heteroaryl or heterocycloalkyl group thereof, and their methods of use. If this group is elected, applicants are requested to elect a single species for the search purpose.

II. Claims 1-14, in part, drawn to compounds/compositions of formula (I), containing compounds of formula (I) not embraced in Group I. If this group is elected, applicants are requested to elect a single species for the search purpose. This group is subject further restriction if it is elected.

It is noted that claim 13 is drawn to "use" claims. Claim 13 provides for the use of derivatives of phosphoric acid ester, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products*, *Ltd. v. Brenner*, 255 F.

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Supp. 131, 149 USPQ 475 (D.D.C. 1966). However, claim 13 herein is drawn to methods of use or processes of making for prosecution of restriction requirement.

Upon thorough consideration of the claims, the examiner has determined that a lack of unity of invention exists, as defined in Rule 13.

PCT Rule 13.1 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention").

PCT Rule 13.2 states that unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B, Part 1(a), indicates that the application should relate to only one invention, or if there is more than one invention, inclusion is permitted if they are so linked to form a single general inventive concept.

Annex B, Part 1(b), indicates that "special technical features" means those technical features which as a whole define a contribution over the prior art.

Annex B, Part 1(c), further defines independent and dependent claims. Unity of invention only is concerned in relation to independent claims. Dependent claims are defined as a claim which contains all the features of another claim and is in the same category as the other claim. The category of a claim refers to the classification of claims according to subject matter, e.g. product, process, use, apparatus, means, etc.

Annex B, Part 1(f) indicates the "Markush practice" of alternatives in a single claim. Part 1(f(i)) indicates the technical interrelationship and the same or

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corresponding special technical feature is considered to be met when: (A) all alternatives have a common property or activity, and (B) a common structure is present or all alternatives belong to a recognized class of chemical compounds. Further defining (B) in Annex B, Part 1(f)(i-iii), the common structure must; a) occupy a large portion of their structure, or b) the common structure constitutes a structurally distinctive portion, or c) where the structures are equivalent and therefore a recognized class of chemical compounds, each member could be substituted for one another with the same intended result. That is, with a common or equivalent structure, there is an expectation from knowledge in the art that all members will behave in the same way. Thus, the technical relationship and the corresponding special technical feature result from a common (or equivalent) structure which is responsible for the common activity (or property). Part 1(f(iv)) indicates that when all alternatives of a Markush grouping can be differently classified, it shall not, taken alone, be considered justification for finding a lack of unity. Part 1(f(v)) indicates that when dealing with alternatives, it can be shown that at least one Markush alternative is not novel over the prior art, the question of unity of invention shall be reconsidered, but does not imply that an objection shall be raised.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted. Again, this list is not exhaustive, as it would be impossible under the time constraints due to the sheer volume of subject matter instantly claimed. Therefore, applicant may choose to elect a single invention by identifying another specific embodiment not listed in the exemplary groups of the invention and examiner will endeavor to group the same.

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The claims herein lack unity of invention under PCT rule 13.1 and 13.2 since the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art, see Austel et al. CAS: 119:117098. Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unit of invention is considered to be proper. Additionally, the vastness of the claimed subject matter, and the complications in understanding the claimed subject matter impose a burden on any examination of the claimed subject matter.

 Applicants are advised that the reply to this requirement to be complete must include an election of invention to be examined even though the requirement be traversed (37 CFR 1.143).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rei-tsang Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph

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K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/REI-TSANG SHIAO /

Rei-tsang Shiao, Ph.D. Primary Patent Examiner Art Unit 1626

June 30, 2008